 (1) a nucleic acid sequence capable of regulating transcription in a host cell, operatively linked to

(2) a chimeric nucleic acid sequence encoding a fusion protein, the chimeric nucleic acid sequence comprising (a) a nucleic acid sequence encoding a pro-peptide derived from an autocatalytically maturing zymogen, linked in reading frame to (b) a nucleic acid sequence heterologous to the pro-peptide and encoding the recombinant polypeptide, wherein the heterologous nucleic acid sequence is located immediately downstream of the nucleic acid sequence encoding the pro-peptide; operatively linked to

(3) a nucleic acid sequence encoding a termination region functional in said host cell,

b) growing the host cell to produce said fusion protein; and


c) adding a mature form of an autocatalytically maturing zymogen to the fusion protein so that the pro-peptide is cleaved from the fusion protein to release the recombinant polypeptide.

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2. A method according to claim 1 wherein said pro-peptide is derived from a protease.

3. A method according to claim 1 wherein said pro-peptide is derived from an aspartic protease, a serine protease or a cysteine protease.

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 4. (Amended) A method according to claim 1 wherein said pro-peptide is derived from a zymogen selected from the group consisting of chymosin, trypsinogen, pepsin, HIV-1 protease, pepsinogen, cathepsin and yeast proteinase A.

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5. A method according to claim 1 wherein the recombinant polypeptide is hirudin or carp growth hormone.

6. The method according to claim 1 wherein the chimeric nucleic acid sequence does not include a sequence encoding a mature form of the zymogen.

~~13~~ 7. (Amended) A method according to claim 1 which further comprises altering the pH, altering the salt concentration or altering the temperature in step (c).

8. A method according to claim 7 wherein the altering the pH comprises altering the pH to a pH from about 2 to about 4.5.

~~14~~ 9. (Amended) A method according to claim 1 wherein step (c) takes place under in vitro conditions.

10. (Amended) A method according to claim 1 wherein step (c) takes place under in vivo conditions.

~~15~~ 11. (Amended) A method according to claim 10 wherein the in vivo conditions take place in a tissue or bodily fluid of an animal.

12. A method according to claim 11 wherein the tissue or bodily fluid comprises the milk, blood, the stomach, the gut or the kidneys of said animal.

~~16~~ 13. (Amended) A method according to claim 1 wherein the mature form of the autocatalytically maturing zymogen added in step (c) is homologous to the pro-peptide.

14. (Amended) A method according to claim 1 wherein the mature form of the autocatalytically maturing zymogen added in step (c) is heterologous to the pro-peptide.

15. The method according to claim 13 wherein the mature zymogen is added under in vitro conditions.

16. The method according to claim 13 wherein the mature zymogen is added under in vivo conditions.

~~17. (Amended) The method according to claim 16 wherein said in vivo conditions take place in a tissue or bodily fluid of an animal.~~

18. The method according to claim 17 wherein the tissue or bodily fluid is a stomach, kidney, gut, blood or milk of said animal.

19. A method according to claim 1 wherein said nucleic acid sequences are deoxyribonucleic acid (DNA) sequences.

20. A chimeric nucleic acid sequence encoding a fusion protein comprising (a) a nucleic acid sequence encoding a pro-peptide from an autocatalytically maturing zymogen and (b) a nucleic acid sequence encoding a polypeptide that is heterologous to the pro-peptide.

21. A chimeric nucleic acid sequence according to claim 20 wherein the pro-peptide is derived from a protease.

22. A chimeric nucleic acid sequence according to claim 20 wherein the pro-peptide is derived from a serine protease, aspartic protease or a cysteine protease.

23. A chimeric nucleic acid sequence according to claim 20 wherein the pro-peptide is derived from chymosin, trypsinogen, pepsin, HIV-1 protease, pepsinogen, cathepsin or yeast proteinase A.

24. A chimeric nucleic acid sequence according to claim 20 wherein the polypeptide is hirudin or carp growth hormone.

25. A chimeric nucleic acid sequence according to claim 20 which does not include a sequence encoding a mature form of the zymogen.

26. A chimeric nucleic acid sequence according to claim 20 wherein said nucleic acid sequences are deoxyribonucleic acid (DNA) sequences.

~~27.~~ (Amended) A chimeric nucleic acid sequence according to claim 26 wherein the chimeric sequence is as shown in SEQ ID NO:1 or SEQ ID NO:3.

28. An expression vector comprising a chimeric nucleic acid sequence according to claim 20 and a regulatory sequence suitable for expression in a host cell.

29. A transformed host cell containing an expression vector according to claim 28.

30. A transformed host cell containing an expression vector according to claim 28 wherein the host cell is a bacterial cell, a fungal cell, a plant cell or an animal cell.

41. A pharmaceutical composition comprising a chimeric nucleic acid sequence encoding a fusion protein, the chimeric nucleic acid sequence comprising (a) a first nucleic acid sequence encoding a pro-peptide derived from an autocatalytically maturing zymogen and (b) a second nucleic acid sequence encoding a polypeptide that is heterologous to the pro-peptide.

42. A food composition comprising a chimeric nucleic acid sequence encoding a fusion protein, the chimeric nucleic acid sequence comprising (a) a first nucleic acid sequence encoding a pro-peptide derived from an autocatalytically maturing zymogen and (b) a second nucleic acid sequence encoding a polypeptide that is heterologous to the pro-peptide.

43. A composition according to claim 41 wherein the nucleic acid sequences are deoxyribonucleic acid (DNA) sequences.

44. A composition according to claim 41 wherein said chimeric nucleic acid sequence does not include a sequence encoding a mature form of the zymogen.